

ATTORNEY DOCKET No.: 2003946-0148 (PITA/US)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Agoulnik *et al.*
Serial No: NYA
Filing Date: July 8, 2004
Corresp. to: PCT/US03/00390
Int. Filing Date: January 8, 2003
Earliest Priority: January 8, 2002
Title: EPONEMYCIN AND EPOXOMICIN ANALOGS AND USES THEREOF

Examiner: NYA.
Group Art Unit: NYA

Mail Stop: PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

<p align="center">Certificate of Express Mailing</p> <p>"Express Mail" label No.: <u>EV 314105049 US</u> Date of Deposit: July 8, 2004</p> <p>I certify that this correspondence is being deposited with the United States Postal Service as "<i>Express Mail Post Office to Addressee</i>" service under 37 C.F.R. 1.10 on the date indicated above and is addressed to: Mail Stop: PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.</p> <p align="center"> _____ Signature Kathy Hart Gagnon _____ Typed or Printed Name of person signing certificate</p>

Sir:

STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- ☒ An *original* Information Disclosure Statement; or
- ☐ A *supplemental* Information Disclosure Statement.

The present Information Disclosure Statement is being filed:

- ☒ Pursuant to 37 CFR § 1.97(b); no fee or certification is required:
- ☒ Within three months of the filing date of a national application other than a continued prosecution application under § 1.53(d);
- ☐ Within three months of the date of entry of the national stage as set forth in § 1.491 in an international application;
- ☐ Before the mailing of a first Office action on the merits; or
- ☐ Before the mailing of a first Office action after the filing of a request for continued examination under § 1.114.
- ☐ Pursuant to 37 CFR § 1.97(c) after the dates listed above but before the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *either*:
- ☐ Certifies that *either*:
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
- ☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

☐ Includes herewith the fee set forth in § 1.17(p).

☐ Pursuant to 37 CFR § 1.97(d), after the mailing date of any of a final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby *both*:

☐ Certifies that *either*:

☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or

☐ That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- ☒ A copy of each cited reference not indicated with a † is included;
- ☐ Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

- ☐ Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the above-identified application:

Applicant certifies that the Information Disclosure Statement *either*:

- ☐ Does not contain non-English language citations;
- ☒ Does contain non-English language citations, of which an English language translation of the Abstract for each is provided herein:

[] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b) .

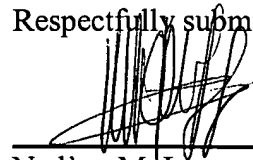
The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,



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Form PTO-1449
(REV. 8-03)U.S. Department of Commerce
Patent and Trademark OfficeAttorney Docket
2003946-0148
(PITA/US)In re Application No.
Not Yet Assigned

10/501120

**INFORMATION
DISCLOSURE STATEMENT**
(Use several sheets if necessary)

Applicant: Agoul'nik *et al*Filing Date:
January 8, 2004Group:
NYA**U.S. PATENT DOCUMENTS**

Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	† 4,990,448	Konishi, et al.	February 5, 1991	435	106
	† 5,071,957	Konishi, et al	December 10, 1991	530	330

U.S. PATENT APPLICATIONS

Examiner's Initials:	Serial Number:	Applicant:	Filing Date:	Group:	Art Unit:

FOREIGN PATENT DOCUMENTS

Examiner's Initials	Document No.	Country	International Publication Date	Translation	
				Yes	No
	EP 0 332 080 B1	EP	September 13, 1989		
	EP 0 411 660 A1	EP	February 6, 1991		
	JP 3-197492	JP	August 28, 1991		X
	JP 5-286955	JP	November 2, 1993		X
	WO 95/24914	PCT	September 21, 1995		
	WO 96/13266	PCT	May 9, 1996		
	WO 02/096933	PCT	December 5, 2002		
	WO 03/033506 A1	PCT	April 24, 2003		X

OTHER DOCUMENTS

Examiner's Initials	Citation (Including Author, Title, Date, Pertinent Pages, Etc.)
	Copy of International Search Report for PCT/US03/00390 A2.
	Adams, et al., "Proteasome Inhibitors: A Novel Class of Potent and Effective Antitumor Agents", <i>Cancer Research</i> , 59 : 2615-2622, 1999.
	Elofsson, et al., "Towards subunit-specific proteasome inhibitors: synthesis and evaluation of peptide α' , β' -epoxyketones, <i>Chemistry & Biology</i> , 6 (11): 811-822, 1999.
	Gardner, et al., "Characterization of peptidyl boronic acid inhibitors of mammalian 20 S and 26 S proteasomes and their inhibition of proteasomes in cultured cells", <i>Biochem J.</i> , 346 : 447-454, 2000.
	Harding, et al., "Novel Dipeptide Aldehydes Are Proteasome Inhibitors and Block the MHC-I Antigen-Processing Pathway ¹ ", <i>The Journal of Immunology</i> , 155 (4):1767-75, 1995.

† Copies of references not included – requirement waived pursuant to USPTO OG Notice of 8/5/03

Form PTO-1449
(REV. 8-03)U.S. Department of Commerce
Patent and Trademark OfficeAttorney Docket
2003946-0148
(PITA/US)In re Application No.
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(Use several sheets if necessary)

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January 8, 2004Group:
NYA

Iqbal, et al., "Potent α -Ketocarboxyl and Boronic Ester Derived Inhibitors of Proteasome", *Bioorganic & Medicinal Chemistry Letters*, **6**(3): 287-90, 1996.

Momose, et al., "Tyropeptins A and B, New Proteasome Inhibitors Produced by *Kitasatospora* sp. MK993-dF2. I. Taxonomy, Isolation, Physico-chemical Properties and Biological Activities", *Journal of Antibiotics*, **54**(12): 997-1003, 2001.

Sin, et al., "Total Synthesis of the Potent Proteasome Inhibitor Epoxomicin: A Useful Tool For Understanding Proteasome Biology", *Bioorganic & Medicinal Chemistry Letters*, **9**(15): 2283-2288, 1999.

Sun, et al., "CEP1612, a Dipeptidyl Proteasome Inhibitor, Induces p21^{WAF1} and p27^{KIP1} Expression and Apoptosis and Inhibits the Growth of the Human Lung Adenocarcinoma A-549 in Nude Mice¹", *Cancer Research*, **61**(4): 1280-1284, 2001.

EXAMINER

DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.